

Public Health Service, HHS

§ 84.70

generally the reasons for such requirements, examinations, inspections, or tests.

[60 FR 30355, June 8, 1995, as amended at 77 FR 14192, Mar. 8, 2012]

§ 84.64 Pretesting by applicant; approval of test methods.

(a) Prior to making or filing any application for approval or modification of approval, the applicant shall conduct, or cause to be conducted, examinations, inspections, and tests of respirator performance which are equal to or exceed the severity of those prescribed in this part.

(b) With the application, the applicant shall provide a statement to the Institute showing the types and results of the examinations, inspections, and tests required under paragraph (a) of this section and state that the respirator meets the minimum requirements of subparts H through KK of this part, as applicable. Complete examination, inspection, and test data shall be retained on file by the applicant and be submitted, upon request, to the Institute.

(c) The Institute may, upon written request by the applicant, provide drawings and descriptions of its test equipment and otherwise assist the applicant in establishing a test laboratory or securing the services of a testing agency.

(d) No approval will be issued until the Institute has validated the applicant's test results.

[60 FR 30355, June 8, 1995, as amended at 77 FR 14193, Mar. 8, 2012]

§ 84.65 Conduct of examinations, inspections, and tests by the Institute; assistance by applicant; observers; recorded data; public demonstrations.

(a) All examinations, inspections, and tests conducted pursuant to subparts H through KK of this part will be under the sole direction and control of the Institute.

(b) The Institute may, as a condition of approval, require the assistance of the applicant or agents of the applicant during the assembly, disassembly, or preparation of any respirator or respirator component prior to testing or

in the operation of such equipment during testing.

(c) Only Institute personnel, persons assisting the Institute pursuant to paragraph (b) of this section, and such other persons as are requested by the Institute or the applicant to be observers, shall be present during any examination, inspection, or test conducted prior to the issuance of an approval by the Institute for the equipment under consideration.

(d) The Institute shall hold as confidential any analyses, drawings, specifications, or materials submitted by the applicant and shall not disclose any principles or patentable features of such equipment, except as required by statute or regulation.

(e) As a condition of each approval issued for any respirator, the Institute reserves the right, following the issuance of such approval, to conduct such public tests and demonstrations of the approved respiratory equipment as is deemed appropriate.

[60 FR 30355, June 8, 1995, as amended at 77 FR 14193, Mar. 8, 2012]

§ 84.66 Withdrawal of applications.

(a) Any applicant may, upon a written request submitted to the Institute, withdraw any application for approval of any respirator.

(b) Upon the receipt of a written request from the applicant for the withdrawal of an application, NIOSH will invoice the applicant based on the fee calculated, as specified under § 84.21(e).

[60 FR 30355, June 8, 1995, as amended at 80 FR 3907, Jan. 26, 2015]

Subpart H—Self-Contained Breathing Apparatus

§ 84.70 Self-contained breathing apparatus; description.

(a) *Limitation on scope.* None of the provisions of Subpart H apply to closed-circuit escape respirators to be approved specifically for escape only from hazardous atmospheres, except as provided for under § 84.304(a)(5). Such respirators are covered under the provisions of subpart O of this part.

(b) Self-contained breathing apparatus, including all completely assembled, portable, self-contained devices